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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/155,023 09/21/98 GUILLE S 2257-137

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HM22/0818

EXAMINER

MCKENZIE, T

ART UNIT

PAPER NUMBER

1624

DATE MAILED:

08/18/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/155,023

Applicant(s)

GUILE ET AL.

Examiner

Thomas McKenzie Ph. D.

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 6/29/00.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 13-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 13, 15, & 16 is/are rejected.
- 7) ☒ Claim(s) 2-9 and 14 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to amendments filed on 6/29/00. There are thirteen claims in the application, claims 1-9 and 13-16. Claims 1, 2, 13, and 14 were rejected in the previous office action. Claims 15 and 16 are new.

Response to Amendment

2. Applicants' amendments are sufficient to overcome the objections to the specification and claims. Those objections are withdrawn. Upon attorney's assurance that applicants' signatures are present in their normal form, the objection to the declaration is withdrawn. Applicants' amendments to the claims are sufficient to overcome the rejections made under USC 112 1st paragraph and those are withdrawn. Please note point #4.

3. Applicants' arguments and amendments to the claims are sufficient to overcome the rejections made under USC 112 2nd paragraph, except as noted below, and those are withdrawn.

Claim Rejections - 35 USC § 112

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Claims 15 and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of the listed diseases, does not reasonably provide enablement for

prevention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The only established prophylactics are vaccines not purine_{2T} antagonists such as present here. Despite intensive efforts, pharmaceutical science has been unable to find a way of getting a compound to be effective for the prevention of cardiovascular diseases generally. Under such circumstances, it is proper for the PTO to require evidence that such an unprecedented feat has actually been accomplished, *In re Ferens*, 163 USPQ 609. No such evidence has been presented in this case. The failure of skilled scientists to achieve a goal is substantial evidence that achieving such a goal is beyond the skill of practitioners in that art, *Genentech vs Novo Nordisk*, 42 USPQ2d 1001, 1006.

5. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the fifth line from the bottom of page 5 and in the first line on page 6 of the amendment, the word "C₁₋₆acyl" is used. Attorney has argued that "the range of 1-6 applies to the carbon chain". This is clear from the recitation C₁₋₆. Acyl is not defined in the specification and applicants did not address the issues of atom type or point of attachment.

6. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim provides for the use of claimed compounds, but the claim does not set forth any steps involved in determining which are the "platelet aggregation disorder [s]". Attorney has argued that the speculative list of diseases spanning line 24, page 12 to line 11, page 14 makes clear which "platelet aggregation disorder [s]" are to be treated. This is not found persuasive. The length of the list alone makes clear that extensive experimentation will be required to determine if a particular disease state responds to any one of applicants' compounds. Attorney has also pointed out that applicants' compounds are postulated to work through a P_{2T} receptor. Determining if a compound, which is efficacious for treatment of a specific disease works by such a mechanism will entail additional experimentation. Further more, in the review on P_2 receptors in "Annual Reports in Medicinal Chemistry, Vol. 31" the only disease contemplated as treatable by a P_{2T} antagonist, which falls into the category of "platelet aggregation disorder [s]" is thrombosis (page 28, sixth complete paragraph). Nowhere does this review discuss the possibility of treating all "platelet aggregation disorder [s]".

Allowable Subject Matter

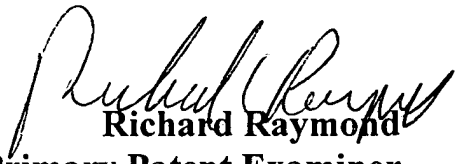
7. Claims 2-9 and 14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

9. Please direct any inquiry concerning this communication or earlier communications from the examiner to Thomas C. McKenzie, Ph. D. whose

telephone number is (703) 308-9806. The examiner can normally be reached on 8:30 to 5:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund J. Shah can be reached on (703) 308-4716. The fax number for the organization where this application is assigned is (703) 308-4556 for regular communications. Please direct any inquiry of a general nature or any inquiry relating to the status of this application to the receptionist whose telephone number is (703) 308-1235.


Richard Raymond
Primary Patent Examiner
Art Unit 1624

TCMcK 
August 13, 2000